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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,104	09/25/2006	Wouter De Graaff	2004.834US	7020

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
08/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@spcorp.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,104	DE GRAAFF ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13-16,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13-16 and 20-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2009 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Grounds of Rejection

Claim Objections

Claim 20 is objected to because of the following informalities: The recitation "when stored on or above room temperature" should be changed to "when stored at or above room temperature" because the latter is grammatically correct. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "for at least approximately 21 days" is indefinite because it is unclear what ranges are encompassed by the phrase. "At least 21 days" is a minimum that encompasses all values at or above 21 days, whereas "approximately 21 days" encompasses values both above and below 21 days.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13-16 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0876815 (EP '815).

EP '815 discloses a drug delivery system comprising at least one compartment comprising (i) a thermoplastic polymer core containing a mixture of progestogenic and estrogenic compounds and (ii) a thermoplastic polymer skin, wherein the thermoplastic polymer skin is permeable to the progestogenic and estrogenic compounds (abstract; page 2, line 50 to page 3, line 12; Examples 1-5). Polyethylene vinylacetate copolymer (Evatane®) is an exemplified material for both the thermoplastic polymer core and thermoplastic polymer skin (page 3, lines 5-8; page 3, lines 26-30; page 4, lines 19-20; Examples 1-5). Etonogestrel (a steroid) is an exemplified progestogenic compound (Examples 1-5). Ethinyl estradiol (a steroid) is an exemplified estrogenic compound (Examples 1-5). The polyethylene vinylacetate copolymer of the core disclosed by EP '815 is a copolymer containing 25 to 35% vinylacetate content (see page 4, lines 3-4). The polyethylene vinyl copolymer of the skin is a copolymer having a thickness of 40 to 300 microns and contains 5 to 15% vinylacetate content (see page 3, lines

54-58). The drug delivery system is ring shaped and is used as a suppository for female contraception (abstract).

The progestogenic compound is dissolved in the core polymer in a relatively low degree of supersaturation, preferably being about 1 to about 6 times of the amount of weight necessary for obtaining the saturation concentration of said progestogenic steroid in said core polymer at 25 ^{o}C (page 2, line 54 to page 3, line 4; claim 4). EP '815 discloses that an essential element of the invention is for the progestogenic steroid dissolved in the core material to be present in a relatively low degree of supersaturation and EP '815 further discloses the importance of keeping the steroid dissolved in a low concentration to improve the shelf life of the product (page 4, lines 6-24; Reference Example).

Regarding instant claims 13-14, '815 discloses a method of manufacturing its drug delivery system comprising the steps of (i) producing a medicated polyethylene vinylacetate copolymer core granulate, comprising a progestogenic and an estrogenic compound, (ii) co-extruding the core granulate with a polyethylene vinylacetate copolymer skin granulate, resulting in a copolymer fiber comprising a core covered by a skin, and (iii) assembling the fiber into a ring (page 4, lines 25-28; Examples 1-5). EP '815 further discloses incorporation of magnesium stearate (a lubricant) into the core granulate (Examples 1-5). EP '815 does not explicitly state that the mixture of core granulate is a homogenous mixture, but the homogeneity of this mixture is inherent in the disclosed invention. This inherency is supported by the need to keep the progestogenic

and estrogenic compounds dissolved in the polyethylene vinylacetate copolymer (page 3, lines 26-27).

Although EP '815 discloses keeping the progestogenic steroid in a relatively low degree of supersaturation and further discloses that keeping the compound in low concentration improves the shelf life of the product, '815 fails to teach the range "up to a concentration below the saturation level at 25 °C" as required by the instant claims.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to find progestogenic steroid concentrations within the range of "up to a concentration below the saturation level at 25 °C" because the range taught by EP '815 touches, if not overlaps with, this range. EP '815 teaches embodiments wherein the concentration of the progestogenic compound is about one times the saturation level at 25 °C (claim 4), and further teaches the importance of keeping the compound dissolved in a low concentration to improve the shelf life. As values are taught around the saturation level at 25 °C, and as EP '815 teaches the importance of keeping the progestogenic steroid dissolved in a low concentration to improve the shelf life, the reference provides sufficient guidance to the ordinary artisan to optimize the progestogenic steroid concentration range to find values just below the saturation level at 25 °C, i.e. values "up to a concentration below the saturation level at 25 °C". "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Regarding instant claim 7 and 20, instant claim 7 is directed to the release profile of etonogestrel from the instant drug delivery system. Instant claim 20 is directed to the shelf life properties of the instant drug delivery system. While EP '815 does not disclose these properties, the drug delivery system rendered obvious by EP '815 is structurally identical to the instant drug delivery system. As a composition cannot be separated from its properties, and the drug delivery system rendered obvious by EP '815 is identical to the instant drug delivery system, the properties disclosed in instant claims 7 and 20 must be inherent in the drug delivery system of EP '815. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). MPEP § 2112.

Regarding instant claim 15, the disclosed kit only requires the presence of the instant drug delivery system. All the recited elements of the kit (i.e. the drug delivery system according to instant claim 1) are rendered obvious by EP '815. Furthermore, EP '815 discloses the role of these elements in contraception and hormone-replacement therapy (page 3, lines 42-43).

Regarding instant claim 16, the disclosed combination preparation only requires the presence of the drug delivery system according to instant claim 1.

All the recited elements of the kit (i.e. the drug delivery system according to instant claim 1) are rendered obvious by EP '815. EP '815 discloses the role of these elements in contraception (page 3, lines 42-43). The Examiner is interpreting "combination" in instant claim 16 to refer to the combination of compartments of the drug delivery system and/or a combination of uses of the drug delivery system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

August 10, 2010